K050182

510(K) Summary

This summary of safety and effectiveness information is submitted in compliance with 21CFR 807.92.

1. **Application Date**: November 30, 2004

AUG 0 9 2005

2. **Applicant Information:**

Biomedix,Inc., USA
40471 Encyclopedia Circle,
Fremont,CA 94538
Establishment Registration No.: 3004525092

Contact Person: Paul K Shieh, Ph.D
Judy S. Chen, Ph.D.
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3. **Trade Names:**

Q.STEPS™ Biometer G/C Dual Monitoring System

4. **Device Description:**

The Q. STEPS™ Biometer G/C Dual Monitoring System uses enzymatic electrochemical biosensor technology for a quick and easy measurement of the whole blood glucose and cholesterol levels. When finger blood is applied to the test spot of the biosensor (test strip), a reduction-oxidation reaction occurs. The oxidation of D-Glucose or Cholesterol which is catalyzed by Glucose Oxidase or by Cholesterol Oxidase respectively, causes an electron transfer at the electrode (silver) surfaces; and therefore, the magnitude of the current produced is proportional to the glucose or cholesterol concentration in the blood. The Biometer G/C uses that current to quantify the glucose and the cholesterol levels in the blood , and then display on the readout of the monitor.

5. **Classification Name:**

Cholesterol test system
Glucose test system
Product Codes: CHH, CGA

6. **Device Classification:**

1. Q.STEPS™ Biometer G/C and Glucose Test Strips – Class II devices (21 C.F.R. §862.1345, Glucose Test System)
2. Q.STEPS™ Biometer G/C and Cholesterol Test Strips – Class I devices (21 C.F.R. §862.1175, Cholesterol Test System)

7. Intended Use

The Q.STEPS Biometer G/C Dual Monitoring System is intended for use with Q.STEPS Glucose and Cholesterol Test Strips with Q.STEPS Biometer G/C by healthcare professionals and home users. Q.STEPS Biometer G/C System provides a quantitative measurement of Glucose and Cholesterol in whole blood from the fingertips. The Glucose measurements are used in helping the management of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia and pancreatic islet cell tumors. Cholesterol measurements are used in the management of disorders involving excess cholesterol in the blood, lipid and lipoprotein metabolism disorders.

8. Reason for 510K

New Device application of 510K Clearance

9. Predicate Devices

The predicate devices for determination of Substantial Equivalence are:

1. Q.STEPS™ Biometer G Blood Glucose Monitoring System (K033627)
2. Polymer Technology Systems, Inc., PTS PANELS Lipid Panel Test Strips (K023558))
3. One Touch Basic/Profile/One Touch II Test Strips, LifeScan, Inc.(K031472)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 9 - 2005

Judy S. Chen, Ph.D.
Consultant
Biomedix, Inc.
40471 Encyclopedia Circle
Fremont CA, 94538

Re: k050182
Trade/Device Name: Q.STEPS Biometer G/C Dual Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA, CHH, JJX
Dated: May 12, 2005
Received: May 16, 2005

Dear Dr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 4

Indications for Use

510(k) Number: K 050182

Device Name: Q. STEPS Biometer G/C Dual Monitoring System

Indications: For Use:The Q.STEPS Biometer G/C Dual Monitoring System is intended for use with Q.STEPS Glucose and Cholesterol Test Strips with Q.STEPS Biometer G/C by healthcare professionals and home users. Q.STEPS Biometer G/C System provides a quantitative measurement of Glucose and Cholesterol in whole blood from the fingertips. The Glucose measurements are used in helping the management of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia and pancreatic islet cell tumors. Cholesterol measurements are used in the management of disorders involving excess cholesterol in the blood, lipid and lipoprotein metabolism disorders.

Prescription Use ____√___ AND/OR Over-The-Counter ___√____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050182